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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,043	10/19/2001	Charles N. Serhan	7214.07	5334

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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,043	SERHAN, CHARLES N.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 17-32 are pending.

2. Claim 1 was cancelled in the Preliminary Amendment of September 30, 2002.

3. Claims 17-32 are rejected.

Response to Arguments

4. Applicant's arguments filed September 30, 2002 have been fully considered but they are not persuasive with respect to the rejection of 35 U.S.C. 112, second paragraph for claims 17-32 as well as the rejection under 35 U.S.C. 103(a) as being unpatentable over Olson et al. in view of Takano et al.

5. Applicant argues that Olson fails to teach any subject matter regarding any treatment associated with such above identified afflictions. In addition, applicant alleges that Olson fails to teach or suggest any motivation to the skilled artisan to use any of the lipoxin analogs as pharmaceuticals capable of modulating a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for the treatment of PLD initiated PMN or for the modulation of a disease/condition associated with PLD initiated superoxide generation or degranulation or for the treatment of PLD initiated superoxide generation. Applicant further argues that Takano et al. fail to teach or suggest to utilize any of the lipoxin analogs to as pharmaceuticals capable of modulating a disease or condition associated with phospholipase D (PLD) initiated polymorphoneutrophil (PMN) inflammation or for the

treatment of PLD initiated PMN or for the modulation of a disease/condition associated with PLD initiated superoxide generation or degranulation or for the treatment of PLD initiated superoxide generation.

6. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art references of Olson et al. and Takano et al., the following response is noted. It is the combination of these references which renders the instant application obvious in view of the rejection under 35 U.S.C. 103(a) as being unpatentable over Olson et al. in view of Takano et al. Accordingly, Olson et al. do teach that PLD can be regulated thereby affecting the activation of the neutrophils, (see pages 3 and 4 of Olson et al.). Also, Takano et al. teach that lipoxin analogs are effective in the inhibiting the PMN, which is critical in inflammation. For these reasons, one having ordinary skill in the art would be motivated from the combined teaching of these references to employ lipoxin analogs to inhibit and modulate PMN responses, as taught by Takano et al., and to further combine this with the Olson et al. teaching that PLD regulation affects the signaling cascade of neutrophils. In addition, the skilled artisan would have been motivated by these combined teachings to treat inflammation, as well as the various types of diseases that are associated with neutrophil activation in the signaling cascade.

Claim Rejections - 35 USC § 112

7. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is removed in response to the amendment of September 30, 2002.

8. The rejection of claims 17-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the variable of R_1 is further defined onto itself, as shown in the group "$C(=O)R_1$" is once again maintained. The variable of R_1 can be defined onto itself repeatedly and indefinitely as currently written. As a result, the present definition does not provide a clear meaning to one skilled in the art.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. in view of Takano et al. Olson et al. teach of the importance of the phospholipase D in the signaling cascade leading to neutrophil activation. In fact, the prior art reference of Olson et al. teaches of regulation of the receptor-regulated phospholipase D in human neutrophils, (pages 3 and 4, under the section entitled Introduction). Takano et al. disclose that the activation of neutrophil (PMN) is critical in inflammation, which suggests of PMN-directed therapies for clinical use, (see abstract).

Takano et al. also teach that lipoxins, such as lipoxin A_4 and aspirin-triggered 15-epi-lipoxin A_4, inhibit human PMN response. This shows that the actions of lipoxin analogs inhibited PMN infiltration in inflammation studies, (see page 819, column 2, paragraph 2). Moreover, the fact that the PMN inflammation is associated with TNF alpha is embraced by the above-stated teachings, in particular Takano et al. because it is well established in the art that cytokines, namely TNF alpha, trigger an inflammatory response, (see Lloyd et al.). In fact, Takano et al. specifically list examples of lipoxin compounds in Figure 2 on page 821. Accordingly, the skilled artisan would have been motivated to utilize the lipoxin analogs of Takano et al. to treat inflammatory diseases associated with TNF alpha since the prior art teaches that there is a connection between neutrophil activation, inflammation and the cytokine of TNF alpha, and consequently a therapy for treating diseases associated with TNF alpha.

11. In addition, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container.

12. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, its is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned. . . In accordance with the patent statutes, an article or composition of

matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

13. Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

14. Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference

between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

15. In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

16. Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

17. The rejection of claims 17-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. in view of Takano et al. is maintained and repeated for both the above-stated and reasons of record. Olson et al. teach of the importance of

the phospholipase D in the signaling cascade leading to neutrophil activation. In fact, the prior art reference of Olson et al. teaches of regulation of the receptor-regulated phospholipase D in human neutrophils, (pages 3 and 4, under the section entitled Introduction). Takano et al. disclose that the activation of neutrophil (PMN) is critical in inflammation, which suggests of PMN-directed therapies for clinical use, (see abstract). Takano et al. also teach that lipoxins, such as lipoxin A_4 and aspirin-triggered 15-epi-lipoxin A_4, inhibit human PMN response. This shows that the actions of lipoxin analogs inhibited PMN infiltration in inflammation studies, (see page 819, column 2, paragraph 2). Moreover, the fact that the PMN inflammation is associated with TNF alpha is embraced by the above-stated teachings, in particular Takano et al. because it is well established in the art that cytokines, namely TNF alpha, trigger an inflammatory response, (see Lloyd et al.). In fact, Takano et al. specifically list examples of lipoxin compounds in Figure 2 on page 821. Accordingly, the skilled artisan would have been motivated to utilize the lipoxin analogs of Takano et al. to treat inflammatory diseases associated with TNF alpha since the prior art teaches that there is a connection between neutrophil activation, inflammation and the cytokine of TNF alpha, and consequently a therapy for treating diseases associated with TNF alpha.

Double Patenting

18. The rejection of claim 1 under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,353,026 is now withdrawn due to the amendment of September 30, 2002.

Obviousness-type Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. The rejection of claims 17-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,353,026 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 6,353,026 also teaches of lipoxin analogs where the substitutents of Q_4H and Q_3H are also hydroxyl groups and embrace all types of stereochemical orientations of these substitutents of Q_4H and Q_3H.

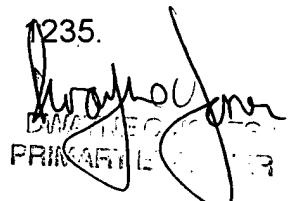
21. The rejection of claims 17-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,441,951 is withdrawn in response to the amendment of September 30, 2002.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-

4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Tech. Ctr. 1614
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